K011208

OCT 0 2 2002

510K Summary

Submitter's name

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Contact person: Heinz E. Wick
EURO CONSULT & ASSOCIATES
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Ridley Park PA. 19078

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Date of Summary prepared

October 10th, 2001

Name of the Device

Trade name: BIOVER
Common/Usual name: BIOVER disposable microvascular clamp

Legally marketed device to which equivilance is claimed

Vas microvascular clamps MICROSURGERY INSTRUMENTS INC.
Bear vessel clamps AROSurgical Instruments Corp.

Description of device

BIOVER disposable microvascular clamp (single or double) made of high-quality material (polycarbonate and stainless steel) was developed for microvascular anastomoses in arterial and venous microsurgery.

Intended use of the Device

For end to end microvascular anastomotic procedures for arteries and veins

The following table shows the different sizes of the BIOVER disposable microvascular clamps
and its use regarding arteries and veins sizes

for arteries

less - 1 mm dia.	TKS 1 + TKS 2
1 mm - 2mm	TKM 1 + TKM 2
2 mm - 4 mm	TKL 1 + TKL 2

for veins

less - 1 mm dia.	TKSV 1 + TKSV 2
1 mm - 2mm	TKMV 1 + TKMV 2

Comparison to predicate Device
The *BIOVER* disposable microvascular clamp is substantially equivalent to the *Bear* vessel clamp as well as the *Vas* microvascular clamp.

a) BEAR vessel clamp distributed by Arosurgical, Newport Beach CA. 92660-2216 is identical to the BIOVER disposable microvascular clamp.
see 510K No. 961100 which was submitted and approved for marketing .

b) VAS microvascular clamp distributed by Microsurgery Instruments INC. Bellaire 77402 is similar to the BIOVER product in design and use, but is not disposable and uses medical grade steel.
see 510K No. 982278 which was submitted and approved for sales.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 2 2002

BIOVER AG
c/o Mr. Heinz E. Wick
Euro Consult & Associates
252 W. Ridley Ave
Ridley Park, PA 19078

Re: K011208
Trade Name: BIOVER Disposable Microvascular Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: August 6, 2002
Received: August 16, 2002

Dear Mr. Wick:

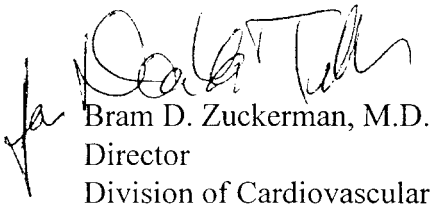
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

Applicant : BIOVER AG.

510-K Premarket Notification **K011208**

Device Name : BIOVER disposable microvascular clamp

Indication for use: BIOVER disposable microvascular clamps are used for end to end anastomotic procedures for arteries and veins.
The single version is placed to stop blood flow for a certain time (less than 16 hrs.)
The double version is used for the repair of ruptured arteries and veins.

The following sizes are used for

a) arteries

less - 1mm dia.	TKS 1 + TKS 2
1mm - 2mm	TKM 1 + TKM 2
2mm - 4mm	TKL 1 + TKL 2

b) veins

less - 1mm dia.	TKSV 1 + TKSV 2
1mm - 2mm	TKMV 1 + TKMV 2

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011208